

REMARKS

Claims 18-28, 31-35 and 39-40 are pending in this application. Claims 18-28, 31-35 and 39-40 were variously rejected under 35 U.S.C. § 103. Claims 18-23, 31-35 and 39-40 were rejected under the judicially created doctrine of obviousness type double patenting.

As issues previously raised are discussed herein, Applicants respectfully request entry of this response.

Applicants thank the Examiner for acknowledging withdrawal of the previous rejections under 35 U.S.C. § 112, second paragraph and §102(b).

Applicants have carefully considered the points raised in the Office Action and believe that the Examiner's concerns have been addressed as described herein, thereby placing this case into condition for allowance.

Rejections under 35 U.S.C. §103

Claims 18-21, 24-28, and 31-35 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Nielsen *et al.* (WO 95/28850, "Nielsen") in view of Ghani (U.S. Pat. No. 6,120,811). Claims 22-23 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Nielsen in view of Ghani and further in view of Markussen *et al.* (U.S. Pat. No. 4,106,991, "Markussen"). Claims 39-40 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Nielsen in view of Ghani and Markussen and further in view of Haarasilta (GB 2-139868A). Applicants respectfully traverse this rejection.

The claimed invention is directed to phytase-containing granulates and to compositions containing the granulates, where the granulates are prepared using an aqueous liquid with a phytase concentration of at least 14,000 FTU per gram aqueous liquid. As described in the specification, Applicants have discovered microorganism culture conditions and filtration steps that result in an

aqueous liquid with the high phytase activity concentration of 14,000 FTU per gram of aqueous liquid or greater. Applicants have also discovered that, when used in the preparation of feed, granulates prepared using the aqueous liquid with such high phytase concentrations result in feed with high pelleting stability of the phytase.

As demonstrated in the Examples of the specification, the phytase in feed prepared with the high phytase granulate as claimed has a much higher pelleting stability than phytase in feed prepared using granulates made with aqueous liquid with a lower phytase concentration. Example 5 describes the preparation of three samples of granulate. The three samples differ in the phytase concentration of the aqueous liquid used in the granulate preparation. Example 10 describes the preparation of three feed mixtures that differ in the granulate used their preparation, pelleting of the three feed mixtures and the determination of the residual phytase activity after pelleting relative to the original phytase activity in the samples. The feed sample containing the granulates made with the high phytase concentration aqueous liquid had the highest pelleting stability.

A *prima facie* case of obviousness requires that three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20USPQ2d 1438 (Fed. Cir. 1991); MPEP §2143. If any one of these three criteria is not met, a *prima facie* case of obviousness has not been established. As presented herein, Applicants respectfully submit that a *prima facie* case of obviousness has not been established.

Nielsen describes an animal feed additive, containing one or more phytase enzymes and one or more proteolytic enzymes, that may be in the form of a granulated enzyme product or in the

form of a liquid composition. Nielsen, page 10, lines 8-24. The Examiner has acknowledged that Nielsen does not teach a phytase-containing granulate comprising an edible carbohydrate polymer. The Examiner has also acknowledged that Nielsen does not teach a liquid phytase solution of 14,000 FTU per gram of liquid.

Further, Nielsen does not provide any information on how to obtain an aqueous liquid preparation with a phytase activity of at least 14,000 FTU per gram of liquid. Nor does Nielsen provide any motivation for the skilled artisan to modify the teaching therein to prepare and use an aqueous liquid with a phytase activity of at least 14,000 FTU per gram of liquid in the compositions of Nielsen. Accordingly, Applicants respectfully submit that Nielsen does not teach or suggest the granulates or compositions as claimed.

The combination of Nielsen with the secondary reference of Ghani does nothing to cure these important defects or to supply what is missing from Nielsen. Ghani describes microgranules containing an enzyme, a carrier such as soy flour, soy grits, corn flour, etc., and other components. Ghani does not teach or suggest a granulate formed by the use of an aqueous liquid comprising a phytase at a concentration of at least 14,000 FTU per gram of aqueous liquid. Ghani provides no information on how to obtain an aqueous liquid preparation with a phytase activity of at least 14,000 FTU per gram of liquid. Nor does Ghani provide any motivation for the skilled artisan to modify the teaching therein to prepare and use an aqueous liquid with a phytase activity of at least 14,000 FTU per gram of liquid.

Applicants respectfully submit that neither Nielsen nor Ghani, alone or in combination, teaches or suggests all the limitations of the claimed invention. Given the silence in the cited references on required elements of the claims, the cited references cannot render the claims obvious.

Further, nothing in Nielsen or Ghani describes the importance of creating compositions with high phytase activity. Thus, Applicants respectfully submit that there is no suggestion or

motivation in Nielsen and/or Ghani to modify the teachings therein to arrive at the claimed invention.

The secondary reference Markussen describes derivatized cellulose in enzyme granulates but does not describe phytase-containing granulates. Markussen does not supply what is missing from Nielsen or from the combination of Nielsen and Ghani. The combination of Nielsen, Ghani and Markussen does not teach or suggest the claimed invention, thus does not render the claimed invention obvious. Further, nothing in Markussen, Nielsen or Ghani describes the importance of creating compositions with high phytase activity and thus, there is no suggestion or motivation in these references to modify the teachings therein to arrive at the claimed invention.

The secondary reference Haarasilta describes granulated cattle fodder with soya bean oil but does not describe phytase-containing granulates. Haarasilta does not supply what is missing from Nielsen or from the combination of Nielsen, Ghani and Markussen. The combination of Nielsen, Ghani, Markussen and Haarasilta does not teach or suggest the claimed invention, thus does not render the claimed invention obvious.

In sum, none of the references, either alone or in combination, describes or suggests the use of a phytase-containing aqueous liquid of at least 14,000 FTU phytase per gram of liquid in the preparation of a granulate having a phytase activity of at least 6000 FTU per gram of granulate. Given the silence in the cited references on required elements of the claims, the cited references cannot render the claims obvious.

Further, Applicants respectfully submit that there is no suggestion in the art or in these references to modify their teachings to arrive at the claimed invention nor do the teachings of the references provide one skilled in the art with a reasonable expectation of the claimed invention.

Accordingly, the cited references do not support *prima facie* obviousness with regard to the claimed invention. Applicants respectfully submit that a *prima facie* case of obviousness has not been established.

Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §103.

Rejection Under Obviousness-Type Double Patenting

Claims 18-23, 31-35, and 39-40 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 7-16 and 22 of U.S. Pat. No. 6,500,426.

Submitted herewith is a terminal disclaimer for the instant application with regard to U.S. Pat. No. 6,500,426.

Accordingly, Applicants respectfully request withdrawal of this rejection.

CONCLUSION

Applicants believe that all issues raised in the Office Action have been properly addressed in this response. Accordingly, reconsideration and allowance of the pending claims is respectfully requested. If the Examiner feels that a telephone interview would serve to facilitate resolution of any outstanding issues, the Examiner is encouraged to contact Applicants' representative at the telephone number below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 251502008600. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: May 3, 2004

Respectfully submitted,

By Karen R. Zachow
Karen Zachow

Registration No.: 46,332
MORRISON & FOERSTER LLP
3811 Valley Centre Drive, Suite 500
San Diego, California 92130
(858) 720-5191